

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT  
Pursuant to Section 13 or Section 15(d)  
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 27, 2024

**AVADEL PHARMACEUTICALS PLC**  
(Exact name of registrant as specified in its charter)

**Ireland**  
(State or other jurisdiction  
of incorporation)

**001-37977**  
(Commission  
File Number)

**98-1341933**  
(IRS Employer  
Identification No.)

**10 Earlsfort Terrace**  
**Dublin 2, Ireland, D02 T380**  
(Address of principal executive offices)

**Not Applicable**  
(Zip Code)

Registrant's telephone number, including area code: **+353 1 901 5201**

**Not Applicable**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation to the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)  
 Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)  
 Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))  
 Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary Shares, nominal value \$0.01 per share	AVDL	The Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 8.01 Other Events.**

On August 27, 2024, the United States District Court for the District of Delaware (the “Court”) issued a decision denying a request by Jazz Pharmaceuticals Inc. (“Jazz”) for a permanent injunction to enjoin Avadel CNS Pharmaceuticals, LLC (“Avadel CNS”), a wholly-owned subsidiary of Avadel Pharmaceuticals plc (the “Company” or “Avadel”), from making, using, selling, offering to sell and/or importing LUMRYZ for its U.S. Food and Drug Administration (“FDA”)-approved indication for the treatment of cataplexy or excessive daytime sleepiness in adults with narcolepsy. Avadel is pleased with the Court’s decision allowing the commercial launch of LUMRYZ in narcolepsy to proceed without interruption.

In addition, the Court granted Jazz’s request preventing Avadel CNS from seeking approval from the FDA for the use of LUMRYZ to treat idiopathic hypersomnia (“IH”) or marketing LUMRYZ for IH through the expiration of US Patent No. 11,147,782. Avadel vehemently disagrees with the Court’s decision regarding IH and has already filed a notice of appeal to the United States Court of Appeals for the Federal Circuit.

Avadel continues to invest in the development of LUMRYZ for IH and is proceeding with the ongoing REVITALYZ Phase 3 study, which was initiated on July 31, 2024, evaluating LUMRYZ as a potential IH treatment, as the Company believes LUMRYZ holds strong potential as an effective and much-needed therapy for IH.

**Cautionary Disclosure Regarding Forward-Looking Statements**

This Current Report on Form 8-K includes “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements relate to our future expectations, beliefs, plans, strategies, objectives, results, conditions, financial performance, prospects or other events. Such forward-looking statements include, but are not limited to, statements regarding the Company’s actions related to the litigation involving Jazz Pharmaceuticals Inc.; the Company’s ongoing REVITALYZ Phase 3 study for LUMRYZ in IH; and the Company’s expectations regarding LUMRYZ as a potential therapy for IH. In some cases, forward-looking statements can be identified by the use of words such as “will,” “may,” “could,” “believe,” “expect,” “look forward,” “on track,” “guidance,” “anticipate,” “estimate,” “project,” “next steps” and similar expressions and the negatives thereof (if applicable).

The Company’s forward-looking statements are based on estimates and assumptions that are made within the bounds of our knowledge of our business and operations and that we consider reasonable. However, the Company’s business and operations are subject to significant risks, and, as a result, there can be no assurance that actual results and the results of the company’s business and operations will not differ materially from the results contemplated in such forward-looking statements. Factors that could cause actual results to differ from expectations in the Company’s forward-looking statements include the risks and uncertainties described in the “Risk Factors” section of Part I, Item 1A of the Company’s Annual Report on Form 10-K for the year ended December 31, 2023, which was filed with the Securities and Exchange Commission (SEC) on February 29, 2024, and subsequent SEC filings. Forward-looking statements speak only as of the date they are made and are not guarantees of future performance. Accordingly, you should not place undue reliance on forward-looking statements. The Company does not undertake any obligation to publicly update or revise our forward-looking statements, except as required by law.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: August 28, 2024

**AVADEL PHARMACEUTICALS PLC**

By: /s/ Jerad G. Seurer

Name: Jerad G. Seurer

Title: General Counsel & Corporate Secretary

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